

REMARKS

The Office Action mailed December 15, 2004, has been carefully reviewed and the foregoing amendment has been made in consequence thereof.

Claims 15-20 are pending in the application. Claims 15-20 stand rejected. Claims 1-14 and 21-29 have been canceled.

In accordance with 37 C.F.R. 1.136(a), a one month extension of time is submitted herewith to extend the due date of the response to the Office Action dated December 15, 2004, for the above-identified patent application from March 15, 2005, through and including April 15, 2005. In accordance with 37 C.F.R. 1.17(a)(1), authorization to charge a deposit account in the amount of \$60.00 to cover this extension of time request also is submitted herewith.

Applicants have amended the specification to indicate that this application is a divisional application of U.S. Patent Application Serial No. 10/052,808 filed November 2, 2001. Accordingly, Applicants have complied with all conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120.

The rejection of Claims 15, 16, and 17 under 35 U.S.C. § 103(a) as being unpatentable over Gambale et al (U.S. Patent No. 5,144,959) is respectfully traversed.

Gambale et al describe a guidewire catheter with varying radiopacity at its distal end. Figure 6 illustrates an embodiment in which the guidewire has a distal tip 62 that is highly radiopaque, a single intermediate segment 64 that is non-radiopaque and a single proximal segment 66 that is moderately radiopaque. The highly radiopaque distal segment 62 provides clear, visible fluoroscopic indication of the distal tip of the guidewire to indicate clearly the guidewire position. Gambale et al explain that "[t]he intermediate, non-radiopaque segment 64 is intended to be disposed so that the region of the artery in which the stenosis is located will be completely unobstructed by any radiopaque effects of the guidewire so that the full radiopaque effect of the radiopaque contrast liquid injected into the artery can be visualized on the fluoroscope, particularly in the critical region of the stenosis." Col. 5, lines 6-13. Accordingly, it is respectfully submitted that Gambale et al do not disclose

nor suggest exposing the core wire beneath the mask at a plurality of predetermined locations.

Claim 15 recites a “method for manufacturing a guidewire suitable for measuring features within a vessel, the method comprising: providing a core wire having proximal and distal sections; coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations; and removing the mask.”

Gambale et al do not describe nor suggest coating portions of the distal section with a mask, exposing the core wire beneath the mask at a plurality of predetermined locations and depositing a radiopaque material at the predetermined locations. Rather, Gambale et al describe a guidewire with varying radiopacity that has three distinct sections. The intermediate section is masked, but the other sections are not. Once the other sections have been electroplated, the mask is removed. As noted above, Gambale et al explain that the intermediate, non-radiopaque segment 64 is intended to be disposed so that the region of the artery in which the stenosis is located will be completely unobstructed by any radiopaque effects of the guidewire so that the full radiopaque effect of the radiopaque contrast liquid injected into the artery can be visualized on the fluoroscope, particularly in the critical region of the stenosis. Accordingly, Gambale teaches away from including multiple elements having radiopaque effects since it could obstruct the stenosis. Again, Gambale does not teach nor suggest exposing the core wire beneath the mask at a plurality of predetermined locations. Accordingly, for the reasons set forth above, Applicants submit that Claim 15 is patentable over Gambale et al.

Claims 16 and 17 depend from independent Claim 15. When the recitations of Claims 16 and 17 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claims 16 and 17 likewise are patentable over Gambale et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103(a) rejection of Claims 15-17 is overcome and should be withdrawn.

The rejection of Claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Gambale et al in view of Schwartz et al (US Patent No. 5,437,288) is respectfully traversed.

Gambale et al is described above. Schwartz et al describe a flexible catheter guidewire that is a solid piece construction. The tip has been cut to create a predetermined pattern of voids which adds greater flexibility to the tip. The patent also describes a lubricious coating of PTFE or hydrogels on the outside of the guidewire. Schwartz et al do not describe nor suggest depositing radiopaque material on the guidewire.

Claim 18 depends from Claim 15 which recites a “method for manufacturing a guidewire suitable for measuring features within a vessel, the method comprising: providing a core wire having proximal and distal sections; coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations; and removing the mask.”

Gambale et al in view of Schwartz et al do not describe nor suggest coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations. Rather, Gambale et al describe a guidewire with varying radiopacity that has three distinct sections. The intermediate section is masked, but the other sections are not. Once the other sections have been electroplated, the mask is removed. Schwartz et al describe a solid guidewire with a flexible tip and a lubricous coating. As noted above, Gambale et al explain that the intermediate, non-radiopaque segment 64 is intended to be disposed so that the region of the artery in which the stenosis is located will be completely unobstructed by any radiopaque effects of the guidewire so that the full radiopaque effect of the radiopaque contrast liquid injected into the artery can be visualized on the fluoroscope, particularly in the critical region of the stenosis. Accordingly, Gambale teaches away from including multiple elements having radiopaque effects since it could obstruct the stenosis. Again, Gambale does not teach nor suggest exposing the core wire beneath the mask at a plurality of predetermined locations and Schwartz et al do not teach nor suggest such an element either..

For the reasons set forth above, Applicants respectfully submit that Claim 15 is patentable over Gambale et al in view of Schwartz et al. Accordingly, since Claim 18 depends from Claim 15, Applicants submit that for at least the reasons set forth above, Claim 18 is patentable over Gambale et al in view of Schwartz et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103(a) rejection of Claim 18 is overcome and should be withdrawn.

The rejection of Claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Gambale et al in view of Tsukada et al (US Patent No. 6,455,783) is respectfully traversed.

Gambale et al is described above. Tsukada et al describe multilayered printed wiring board and method for manufacturing same. The circuit board is formed by a plurality of steps that includes, at one point, applying a mask and applying a solvent to the mask to dissolve and remove the mask. Tsukada et al is not directed towards guidewires and is considered to be non-analogous art in the field of guide wires.

Claim 19 depends from Claim 15 which recites a “method for manufacturing a guidewire suitable for measuring features within a vessel, the method comprising: providing a core wire having proximal and distal sections; coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations; and removing the mask.”

Gambale et al in view of Tsukada et al do not describe nor suggest coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations. Rather, Gambale et al describe a guidewire with varying radiopacity that has three distinct sections. The intermediate section is masked, but the other sections are not. Once the other sections have been electroplated, the mask is removed. Tsukada et al describe a method of applying a mask and removing the mask. As noted above, Gambale et al explain that the intermediate, non-radiopaque segment is intended to be disposed so that the region of the artery in which the stenosis is located will be completely unobstructed by any radiopaque effects of the guidewire so that the full radiopaque effect of the radiopaque contrast liquid injected into the artery can be visualized on the fluoroscope, particularly in the critical region of the stenosis. Accordingly, Gambale teaches away from including multiple elements having radiopaque effects since it could obstruct the stenosis. Again, Gambale does not teach nor suggest exposing the core wire beneath the mask at a plurality of predetermined locations and Tsukada et al is considered to be non-analogous art. As well, Tsukada et al do not teach nor suggest such an element either.

As is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. The required teachings, suggestions and incentives supporting the Examiner's combinations are absent here. Neither Gambale et al nor Tsukada et al teach or suggest the claimed subject matter. Furthermore, in contrast to the assertion within the Office Action, Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Gambale et al with Tsukada et al because there is no motivation to combine these references suggested in the art. The Examiner has not pointed to any prior art that teaches or suggests combining the disclosures.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicant's disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicant's disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion nor motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown. Specifically, the Examiner has indicated that it "would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the mask as disclosed by Gambale et al by chemically dissolving the as taught by Tsukada et al so as to remove the mask in its entirety." Office Action mailed December 15, 2004, p. 4. Applicants respectfully submit that neither Gambale et al nor Tsukada et al provide motivation to remove a mask from a guidewire with a chemical process.

Furthermore, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the cited art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejection is apparently based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention.

Since there is no teaching, suggestion, or motivation in the cited references for the claimed combinations recited in Claim 19, the Section 103 rejections of Claim 19 appears to be based on an impermissible hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible.

For the reasons set forth above, Applicants respectfully submit that Claim 15 is patentable over Gambale et al in view of Tsukada et al. Accordingly, since Claim 19 depends from Claim 15, Applicants submit that for at least the reasons set forth above, Claim 19 is patentable over Gambale et al in view of Tsukada et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103(a) rejection of Claim 19 is overcome and should be withdrawn.

The rejection of Claim 20 under 35 U.S.C. § 103(a) as being unpatentable over Gambale et al in view of Sanchez et al (US Patent No. 6,636,758) is respectfully traversed.

Gambale et al is described above. Sanchez et al describe a marker wire and process for using it. The wire includes a distal tip having radiopaque markers. In one embodiment, the marker bands are placed over a section of constant radius core wire. In another embodiment, the marker bands are placed in an appropriate position and then melted into place. In a further embodiment, the marker bands are of a material that does not melt during their placement. However, these bands are placed on a polymer coating and have a layer of polymer between the interior of the marker bands and the core wire. (See Figure 3B). Accordingly, Sanchez et al do not show exposing the core wire beneath the mask, forming indentations at the locations and depositing the radiopaque material.

Claim 20 depends from Claim 15 which recites a “method for manufacturing a guidewire suitable for measuring features within a vessel, the method comprising: providing a core wire having proximal and distal sections; coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations; and removing the mask.”

Gambale et al in view of Sanchez et al do not describe nor suggest coating portions of the distal section with a mask; exposing the core wire beneath the mask at a

plurality of predetermined locations; depositing a radiopaque material at the predetermined locations. Rather, Gambale et al describe a guidewire with varying radiopacity that has three distinct sections. The intermediate section is masked, but the other sections are not. Once the other sections have been electroplated, the mask is removed. Sanchez et al describe a marker wire with marker bands placed on or in a polymer coating that surrounds a core wire. As noted above, Gambale et al explain that the intermediate, non-radiopaque segment is intended to be disposed so that the region of the artery in which the stenosis is located will be completely unobstructed by any radiopaque effects of the guidewire so that the full radiopaque effect of the radiopaque contrast liquid injected into the artery can be visualized on the fluoroscope, particularly in the critical region of the stenosis. Accordingly, Gambale teaches away from including multiple elements having radiopaque effects since it could obstruct the stenosis. Again, Gambale does not teach nor suggest exposing the core wire beneath the mask at a plurality of predetermined locations and neither do Sanchez et al.

In addition, Claim 20 recites “forming indentations at the predetermined locations prior to depositing the radiopaque materials.” Gambale et al in view of Sanchez et al do not teach nor suggest such a method step. Specifically, Sanchez et al do not teach nor suggest forming indentations at predetermined locations. There is not suggestion within Sanchez of indentations in the core wire and accordingly Gambale et al in view of Sanchez et al do not teach nor suggest the recitations provided in Claim 20.

For the reasons set forth above, Applicants respectfully submit that Claim 15 is patentable over Gambale et al in view of Sanchez et al. Accordingly, since Claim 20 depends from Claim 15, Applicants submit that for at least the reasons set forth above, Claim 20 is patentable over Gambale et al in view of Sanchez et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103(a) rejection of Claims 20 is overcome and should be withdrawn.

The rejection of Claims 15, 16, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Frechette et al (US Patent No. 5,144,959) in view of Gambale et al is respectfully traversed.

Frechette et al describe a guidewire with a compound tapered tip. The tip construction allows the guidewire to proceed in a generally straight direction rather than

follow side branches of the vessel. Frechette also describes that a lubricious coating may be applied to the guidewire. Also, Frechette describes that the tip may be electroplated with a radiopaque material for visibility during placement. However, Frechette does not describe coating portions of the guidewire with a mask and exposing the core wire beneath the mask at a plurality of locations.

Gambale et al is described above.

Claim 15 recites a “method for manufacturing a guidewire suitable for measuring features within a vessel, the method comprising: providing a core wire having proximal and distal sections; coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; depositing a radiopaque material at the predetermined locations; and removing the mask.”

Frechette et al in view of Gambale et al do not describe nor suggest coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; and depositing a radiopaque material at the predetermined locations. Rather, Gambale et al describe a guidewire with varying radiopacity that has three distinct sections. The intermediate section is masked, but the other sections are not. Once the other sections have been electroplated, the mask is removed. Gambale et al do not describe exposing the core wire beneath the mask at a plurality of locations or depositing a radiopaque material at the predetermined locations. Frechette et al describe a guidewire with a compound tapered tip. Frechette do not describe nor suggest coating portions of the distal section with a mask; exposing the core wire beneath the mask at a plurality of predetermined locations; and depositing a radiopaque material at the predetermined locations. As noted above, Gambale et al explain that the intermediate, non-radiopaque segment is intended to be disposed so that the region of the artery in which the stenosis is located will be completely unobstructed by any radiopaque effects of the guidewire so that the full radiopaque effect of the radiopaque contrast liquid injected into the artery can be visualized on the fluoroscope, particularly in the critical region of the stenosis. Accordingly, Gambale teaches away from including multiple elements having radiopaque effects since it could obstruct the stenosis. Again, Gambale does not teach nor suggest exposing the core wire beneath the mask at a plurality of predetermined locations and neither

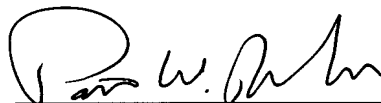
do Frechette et al. For the reasons set forth above, Applicants respectfully submit that Claim 15 is patentable over Frechette et al in view of Gambale et al

Claims 16, 17, and 18 depend from independent Claim 15. When the recitations of Claims 16, 17, and 18 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claims 16, 17, and 18 likewise are patentable over Frechette et al in view of Gambale et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103(a) rejection of Claims 15, 16, 17, and 18 is overcome and should be withdrawn.

In view of the foregoing amendments and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully submitted,



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